A
New 510(k)
Paradigm

Alternate Approaches
to Demonstrating Substantial Equivalence
in Premarket Notifications

Prepared by the
510(k) Reengineering Team
Center for Devices and Radiological Health

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U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

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in Premarket Notifications

Introduction

As a part of the Center for Devices and Radiological Health's (CDRH) organizational transformation initiative, the 510(k) Process Reengineering Team has been examining the existing process through which regulated industry demonstrates substantial equivalence of medical devices in premarket notifications (510(k)s). As presented below in "A New 510(k) Paradigm," the Team has concluded that there are optional approaches to the traditional method of demonstrating substantial equivalence. These alternative approaches are within the existing statutory framework, and it is anticipated that they will conserve the Agency's review resources while facilitating the introduction of safe and effective devices into interstate commerce.

Background

Under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act), a person who intends to introduce a device into commercial distribution is required to submit a premarket notification, or 510(k), to FDA at least 90 days before commercial distribution is to begin. Section 513(i) of the Act stipulates that FDA may issue an order of substantial equivalence, only upon making a determination that the device to be introduced into commercial distribution is as safe and effective as a legally marketed device. Under 21 CFR 807.87, FDA has codified the content requirements for premarket notifications to be submitted by device manufacturers in support of the substantial equivalence decision. FDA has, however, discretion in the type of information it deems necessary to meet those content requirements. For example, to more effectively allocate review resources to the highest risk devices, FDA developed a tiering system based on the level of risk posed by medical devices. Under this system, the substantial equivalence determination for low risk devices is based primarily on descriptive information and a labeling review, while the decision for higher risk devices relies on performance data.

In a further effort to manage FDA's workload and allocate its resources most appropriately, the agency has exempted certain Class I devices from the requirement for premarket notification. Since the passage of the Medical Device Amendments in 1976, FDA has exempted 573 generic types of devices from the requirement of premarket notification. The Agency may propose this action if, based on the existing and reasonably foreseeable characteristics of commercially distributed devices within a generic type, FDA determines that premarket notification is unnecessary for the protection of public health.

Currently, CDRH is evaluating the 221 Class I devices that remain subject to premarket notification requirements to see which, if any, of these devices should be proposed for exemption. Similarly, the Center is examining Class II devices to see if any of these devices could be reclassified to Class I and exempted from 510(k). Following these efforts, it is anticipated that the Class I devices remaining subject to premarket notification will be proposed for reclassification to Class II subject to special controls.

The last phase of this effort involves the preamendments Class III devices. Preamendments Class III devices for which general controls or special controls are sufficient to ensure safety and effectiveness will be down-classified to either Class I/ 510(k) exempt or to Class II, respectively. Those preamendments Class III devices which cannot be reclassified will remain in that class and be subject to either premarket approval (PMA) or product development protocol (PDP) requirements. It is anticipated that, as a result of this reclassification effort, the premarket notification process will be reserved for Class II devices exclusively.

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Under this proposed classification scheme in which Class I devices will be 510(k) exempt, Class II devices will be subject to premarket notification, and Class III devices will be subject to either PMA or PDP, the 510(k) Reengineering Team has developed "A New 510(k) Paradigm." Attachment 1 outlines the new paradigm which presents device manufacturers with several optional approaches for obtaining marketing clearance for their Class II devices. While this proposal maintains the traditional method of demonstrating substantial equivalence under section 510(k) of the Act, it also presents two alternatives. The first alternative, the "Special 510(k): Device Modification," utilizes certain aspects of the Quality System regulation, while the second alternative, the "Abbreviated 510(k)," relies on the use of special controls and consensus standards to facilitate 510(k) review.

A. Special 510(k): Device Modification

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629) amended section 520(f) of the Act, providing FDA with the authority to issue regulations requiring pre-production design controls. Specifically, section 520(f)(1)(A) states that FDA may prescribe regulations to require "that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act." This change in the law was based on findings that a significant proportion of device recalls were attributed to faulty design. Pursuant to the authority provided by the SMDA, FDA revised its current good manufacturing practice requirements to include pre-production design controls that device manufacturers must follow when initially designing devices or when making subsequent modifications to those designs. (See 21 CFR 820.30)

Effective June 1, 1997, manufacturers of Class II and certain Class I devices must follow design control procedures for their devices, including device modifications. Product modifications that could significantly affect safety and effectiveness are subject to 510(k) submission requirements under 21 CFR 807 as well as design control requirements under 21 CFR 820.30. In accordance with the Quality System regulation, manufacturers must have a systematic set of requirements and activities for the management of design and development, including documentation of design inputs, risk analysis, design output, test procedures, verification and validation procedures, and documentation of formal design reviews. In this process, the manufacturer must ensure that design input requirements are appropriate so the device will meet its intended use and the needs of the user population. The manufacturer must also establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Thus, manufacturers may need to refine their device design requirements as verification and validation results are obtained. The design specifications that result from this process are the design outputs which form the basis for the device master record (DMR) which is subject to inspection by FDA personnel.

Since design controls are now in effect and require the conduct of verification and validation studies of a type that have traditionally been included in 510(k) submissions, the 510(k) Reengineering Team is proposing that test results generated pursuant to the new design control requirements will be sufficient to serve as a basis for certain substantial equivalence decisions. In light of the design control requirements, the Team believes that it may be appropriate, in certain circumstances, to forgo a detailed review of the underlying data normally required in 510(k)s. While FDA would not rely on the design controls procedure requirements to issue a determination of substantial equivalence, it would rely on the existence of data generated in accordance with those procedures to issue a substantial equivalence determination. For this reason, the Team is proposing that conformance with design controls could be used an alternative to the traditional method of demonstrating substantial equivalence for certain device modifications.

Under the proposed 510(k) Paradigm, a manufacturer would use the FDA guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" to decide if a device modification could be implemented without submission of a new 510(k). If a new 510(k) is needed for the modification and if the modification does not affect the intended use of the device or the basic fundamental scientific technology of the device, conformance with design controls could form the basis for clearing the application.[1]

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[1] The terms "intended use" and "basic fundamental scientific technology" are used in the same manner as when used to define the limitations of exemptions from section 510(k) of the Act as found in each of the product classification regulations, 21 CFR 862-892, e.g., 21 CFR §§862.9, 864.9, and 866.9)

Under this option of the Paradigm, a manufacturer who is intending to modify his/her own legally marketed Class II device would conduct the necessary verification and validation activities (as determined by a risk analysis) to demonstrate that the design outputs of the modified device meet the design input requirements. Once the manufacturer has ensured the satisfactory completion of this process through design review, a "Special 510(k): Device Modification" could be submitted. While the basic content requirements of the 510(k) (21 CFR 807.87) would remain the same, this type of submission should also reference the cleared 510(k) number and contain a "Declaration of Conformity" with design control requirements[2]. Refer to Attachment 2 for the contents of a "Special 510(k): Device Modification" with a "Declaration of Conformity" to design controls.

In the Special 510(k), a manufacturer would also have the option of using a third party to assess conformance with design controls. In this case, the third party would perform a conformance assessment for the device manufacturer and provide the manufacturer with a statement to this effect. The marketing application would then include both the statement from the third party as well as a declaration of conformity signed by the manufacturer.

In order to provide an incentive for device manufacturers to chose this option for obtaining Agency clearance for these types of device modifications, Special 510(k)s will be processed by the Office of Device Evaluation (ODE) within 30 days of receipt by the Document Mail Center (DMC). A manufacturer's declaration of conformity with design controls will allow the Agency to review modifications that do not affect the device's intended use or the device's basic fundamental scientific technology within this abbreviated time frame. The Team does not believe that modifications which affect the intended use or alter the basic fundamental scientific technology of the device are appropriate for review under this type of application but rather should continue to be subject to routine 510(k) procedures or may be subject to an "Abbreviated 510(k)" as described below.

B. Abbreviated 510(k)

The SMDA of 1990 introduced the concept of special controls as the means by which the safety and effectiveness of Class II devices can be assured. Special controls are defined by the statute as those controls, such as performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations and other appropriate actions that provide reasonable assurance of the device's safety and effectiveness.

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[2] Those parties who currently have sole ownership of a cleared 510(k) (this may be an acquired ownership) or manufacturers of preamendments devices subject to premarket notification may submit Special 510(k)s. See Attachment 2 for specific content requirements.

While, to date, CDRH has not identified specific special controls for particular devices, except when reclassifying a Class III device to Class II, considerable effort has been expended to develop the concept of a "special control guidance document" (SCGD). Under this initiative, reasonably foreseeable risks that are associated with a type of Class II device would be identified in a SCGD. For each risk, the Agency would also identify a special control(s) such as a consensus standard, labeling content, or postmarket surveillance that would address the risk. SCGDs would be developed in accordance with the Agency's Good Guidance Practices and thus would be a collaborative effort between all interested parties.

In addition to SCGDs that would be developed for generic Class II devices, CDRH is committed to recognizing individual consensus standards. The consensus standards could be cited in SCGDs, recognized in individual policy statements, or identified as "special controls" that address specific risks associated with multiple device types. IEC 60601 is an example of such a consensus standard. It has broad applicability to many electromedical devices. FDA's recognition of this standard, combined with modified review procedures, could streamline the review of many 510(k)s for devices covered by the standard. Finally, by using the accompanying particular standards to adapt the general standard to specific devices, the 510(k) review process may be further expedited.

Under this proposal, device manufacturers could chose to submit "Abbreviated 510(k)s" for Class II devices when a SCGD exists or when FDA has recognized an individual special control such as a relevant standard. In addition to the required elements of a 510(k) (21 CFR 807.87), these abbreviated submissions would include summary information that describes how "special controls" have been used to address the risks associated with the device type and a declaration of conformity with any relevant recognized standard(s), if applicable. As seen in Attachment 4, a declaration of conformity with a standard would provide a summary of the manufacturer's efforts to conform with the recognized standard and would outline any deviations.

In an Abbreviated 510(k), a manufacturer would also have the option of using a third party to assess conformance with the recognized standard. Under this scenario, the third party would perform a conformance assessment to the standard for the device manufacturer and provide the manufacturer with a statement to this effect. The marketing application would then include both the statement from the third party as well as summary information and a declaration of conformity signed by the manufacturer.

The incentive for manufacturers to elect to use special controls or to declare conformance to recognized standards would be a more expedient review of their submissions. While abbreviated submissions will compete with routine 510(k) submissions, it is anticipated that their review will be more timely and efficient than that of traditional submissions which tend to be data intensive. In addition, by allowing ODE reviewers to rely on a manufacturer's use of special controls, including conformance with recognized standards, review resources can be directed at more complicated issues and thus should expedite the process.

Conclusion

The 510(k) Process Reengineering Team believes that the "New 510(k) Paradigm" can be implemented through changes in the administrative process and does not require changes either to the premarket notification regulation (21 CFR 807 Subpart E Premarket Notification Procedures) or to the Act, although legislative reform may facilitate its implementation. Interested parties should recognize that implementation procedures have not yet been developed and such procedures may depend in part on comments received. It is anticipated that the Paradigm, or selected aspects of it, could be implemented as soon as the Fall of 1997.

At this time, the Team is soliciting comments on the proposed Paradigm. General comments on the concept as well as specific comments are welcome. The Team is especially interested in comments as to whether the information identified under the Summary of Design Control Activities section of Attachment 2: (1) appropriately summarizes the information needed for the Special 510(k) option of the Paradigm to be a viable alterative to the traditional method of demonstrating substantial equivalence; and (2) is appropriately inclusive without being overly burdensome.

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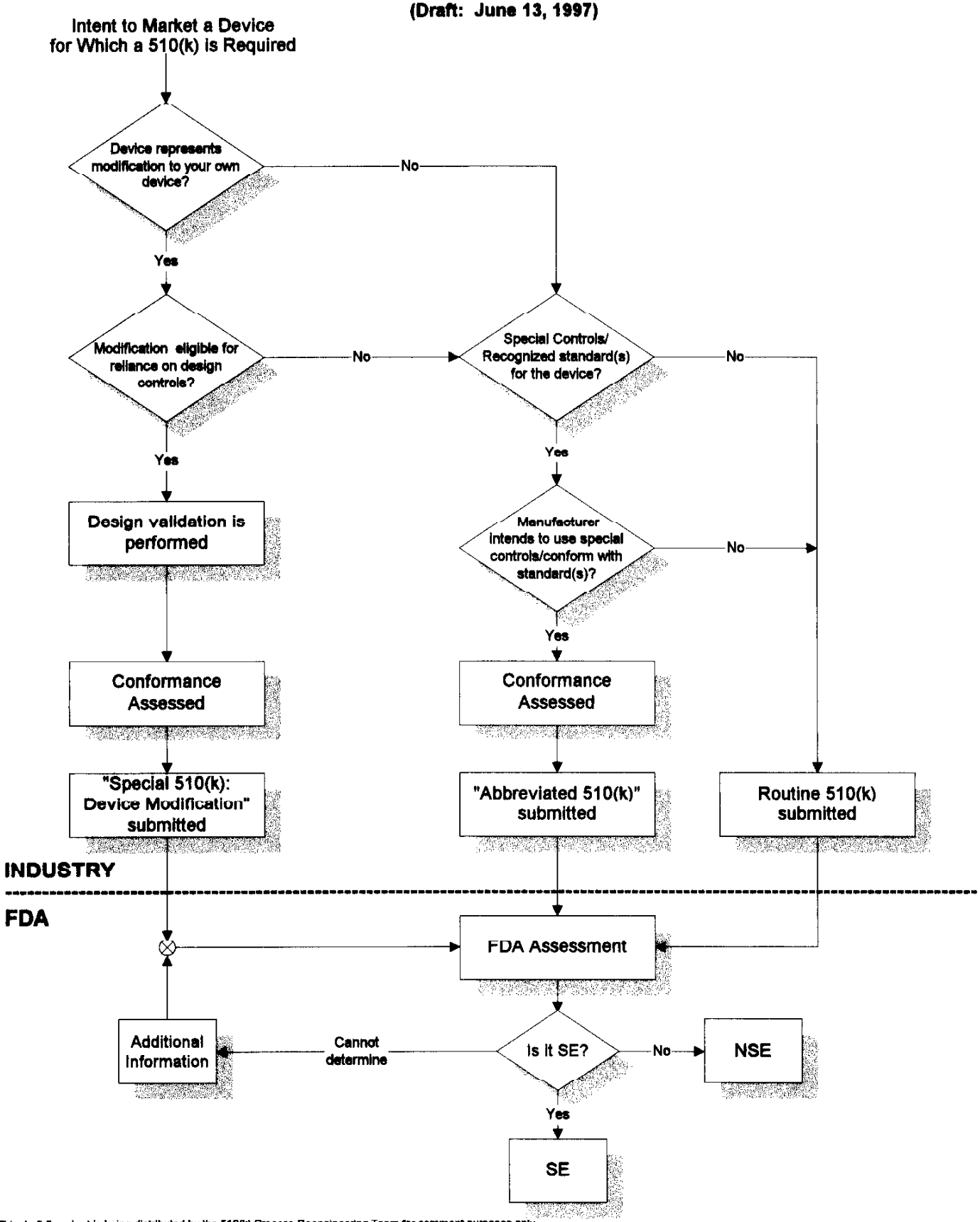

**This draft flowchart is being distributed by the 510(k) Process Reengineering Team for comment purposes only. This flowchart should only be considered in conjunction with the accompanying proposed text.

Attachment 2
"Special 510(k): Device Modification"

A Special 510(k): Device Modification should include:

- A coversheet clearly identifying the application as a "Special 510(k): Device Modification;"
- The name of the legally marketed (unmodified) device and the 510(k) number under which it was cleared[3,4];
- Items required under §807.87 (a)-(f), (h), (j), and (k) including a description of the modified device and a comparison to the cleared device, the intended use of the device, and the proposed labeling for the device;
- A summary of design control activities[5]. This should include the following:
    - Identification of the Risk Analysis method(s) used to assess the impact of the modification on the device and its components and the results of the analysis;
    - Based on the Risk Analysis, an identification of the verification and/or validation activities required (including methods or tests used) and documentation that these activities were performed by the designated individual(s) and that the results demonstrate that predetermined acceptance criteria were met;
    - Identification of any manufacturing process controls added/changed as a result of the modifications to the device (e.g., new work instructions, operator retraining, equipment re-qualification, new inspection aids, additional sampling, etc.)

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[3] For preamendments devices subject to premarket notification requirements, the manufacturer should clearly state that the device is a preamendments device, is legally marketed, and has not been the subject of premarket notification clearance. (Refer to "Documentation Required for Preamendments Status" for the procedures for demonstrating preamendments status. Manufacturers should maintain this information in their files.)

[4] For manufacturers who have purchased a cleared 510(k) or a preamendments device, the Special 510(k) should also include adequate information to demonstrate the transfer of ownership from the original 510(k) holder to the submitter of the current 510(k), including any interim transfers.

[5] FDA would consider this summary information to be "appropriate supporting data," within the meaning of §807.87(g).

Attachment 2
"Special 510(k): Device Modification"
(Continued)

- Identification of changes made to the Device Master Record (DMR) related to the modified device -- provide document number(s) and revision level(s);

- Documentation of final design review and sign-off of modified device by designated individual(s); and

- Declaration of conformity with design controls[6].

- Indications for use enclosure

[6] If a recent Quality System inspection has resulted in the issuance of a violative inspection report, the manufacturer should be prepared to describe those corrective actions taken that form the basis for the declaration of conformity.

Attachment 3
"Abbreviated 510(k)"

An Abbreviated 510(k) should include:

- A coversheet clearly identifying the application as an "Abbreviated 510(k);"

- Items required under §807.87 (a)-(h), (j), and (k) including a description of the device, the intended use of the device, and the proposed labeling for the device;

- Summary information that describes how "special controls" have been used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternative approach to addressing a particular risk, sufficient detail should be provided to justify the deviation.)

- If a manufacturer is declaring conformity to a recognized standard, the declaration should be submitted in accordance with Attachment 4.

- Data/information to address issues not covered by special controls including recognized standards.

- Indications for use enclosure

Attachment 4
Declaration of Conformity

A declaration of conformity to a recognized standard should clearly specify the following:

- Any element of the standard that was not applicable to the device;
- If the standard is part of a family of standards which includes collateral and/or particular parts, a statement regarding the collateral and/or particular parts that were met;
- Any deviations from the standards that were applied;
- What differences exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference; and
- Name and address of any test laboratory or certification body involved and a reference to any accreditations of those organizations.